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## **REMARKS**

### **I. Procedural History**

Claims 1 and 43-53 are now pending. Previously, claim 1 (pending) and claim 35 (canceled) were the only two claims pending in the referenced U.S. Patent Application Serial No. 09/690,044 (the "'044 application"). Claims 1 and 35 were allowed, and a Notice of Allowance was issued in the '044 application on 10 October 2003. The Issue Fee due date was 12 January 2004. The Issue Fee was not paid. Rather, on December 23, 2003, Applicants filed an Information Disclosure Statement ("IDS") concurrently with a Request for Continued Examination ("RCE") pursuant to 367 C.F.R. §1.114(a)(1). A supplemental Notice of Allowance was issued on January 14, 2004. Applicants filed a supplemental IDS on 19 March 2004.

Subsequent to the filing of the RCE and the re-opening of examination, no Office Action has been issued with respect to a substantive examination of the claims on the merits.

Accordingly, Applicants submit this Preliminary Amendment for the Examiner's consideration prior to the issuance of the first Action on the merits.

### **II. Claim Amendments**

The claimed compound is an optically pure magnesium salt of the (-)-enantiomer of omeprazole. By the expression "optically pure", it is meant that that the claimed magnesium salt of the (-)-enantiomer of omeprazole is essentially free of the magnesium salt of the (+)-enantiomer of omeprazole (See page 5, lines 16-19).

Claim 1 has been amended to recite that the claimed compound is characterized by an optical purity of at least about 94% enantiomeric excess (e.e.). New claims 43-53 have been

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added. Claim 43 provides that the optical purity of the compound of claim 1 is at least 94% e.e. Claim 44 provides that the compound of claims 1 and 43 is in crystalline form. New claims 45-53 are directed to embodiments wherein the claimed compound is characterized by an optical purity of at least about or at least 98.4% e.e., 99.8% e.e. or 99.9% e.e.

Support for the claim amendments is provided by the specification where it is disclosed that the claimed compound can be obtained in a very high optical purity, e.g., 99.8% e.e. (See p.5, lines 23-27). Furthermore, Examples 5, 6 and 12 disclose the following degrees of optical purity:

CLAIMED COMPOUND: $\text{Mg}^{2+}$ of (-)-omeprazole		
Example	Recovered Compound	Optical Purity (reported e.e.)
5	$\text{Mg}^{2+}$ of (-)-omeprazole	99.9%
6	$\text{Mg}^{2+}$ of (-)-omeprazole	98.4%
12	(-)-omeprazole	94%

Additional support is provided by original claim 32 which provides that the claimed compound can be prepared in an optically pure form from the (-)-enantiomer of omeprazole, e.g., the compound of Example 12 having a reported optical purity of 94% e.e.

It is submitted that the expression "at least about", as recited in claims 1, 45, 48 and 51, is fully supported by the specification and is not indefinite. Although the term "about" is not expressly used when disclosing the optical purity of the claimed invention, the use of the term "about" in claims 1, 45, 48 and 51 does not constitute a change to a distinct and different invention as originally disclosed. The originally filed specification clearly indicates to persons skilled in the art that Applicants were in possession of what is now claimed as of the filing date.

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Therefore, the term "about", as used in claims 1, 45, 48 and 51, cannot properly be construed as new matter.

Rather, "about" is used in claims 1, 45, 48 and 51 as a descriptive term to avoid what would be an unfair and unnecessary boundary of the disclosed optical purity of the claimed invention, e.g., the reported optical purity of the recovered compounds of Examples 5, 6 and 12. Such a usage of the term "about" has been upheld by the Federal Circuit to be permissible and not indefinite. *Verve, LLC, v. Crane Cams, Inc.*, 311 F.3d 1116 (Fed. Cir. 2002).

For all of the foregoing reasons, Applicants submit that no new matter is introduced by the claim amendments.

### **III. Clarification**

For the sake of clarity and to remove any ambiguity from the record, Applicants respectfully wish to address the Examiner's statement appearing in the supplemental Notice of Allowance that "[i]n view of the highly stable complex between magnesium and omeprazole, it is unobvious to obtain the single non-complexed salt of the instant claim".

The Examiner is correct in stating that magnesium and omeprazole racemate form a highly stable complex. This complex is a result of the divalent nature of the metal magnesium ion ( $Mg^{2+}$ ) which acts as a coordination or complexing agent to form a complex with the (+)- and (-)-enantiomers of omeprazole. The result is a complex and magnesium salt of omeprazole racemate.

In view of this highly stable complex between magnesium and omeprazole racemate, the Examiner states that it was unobvious to obtain "the single non-complexed salt" of the claimed

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invention. Applicants agree that the prior art neither discloses nor suggests the claimed magnesium salt of (-)-omeprazole. However, Applicants respectfully submit that the characterization of the claimed compound as a "non-complexed" salt is not correct.

The magnesium ion ( $Mg^{2+}$ ) is divalent and, therefore, it has two (2) units of combining power. In the case of the racemate, the magnesium ion ( $Mg^{2+}$ ) complexes with two (2) molecules, i.e., the (+)- and (-)-enantiomers of omeprazole, to form a complex and salt of omeprazole racemate. With respect to the claimed invention, the magnesium ion ( $Mg^{2+}$ ) also complexes with two (2) molecules. However, in the claimed invention, the two molecules are both the (-)-enantiomer of omeprazole. The result is a complex and magnesium salt of (-)-omeprazole.

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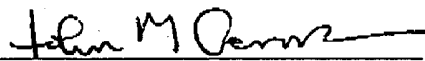
**CONCLUSION**

Pending claims 1 and 43-53 are directed to patentable subject matter. Allowance of the claims is respectfully requested.

Any fee required in connection with this communication may be charged to Deposit Account No. 23-1703.

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Respectfully submitted,



John M. Genova  
Reg. No. 32,224  
Attorney for Applicants

Customer No. 07470  
Attorney Direct Dial: (212) 819-8832